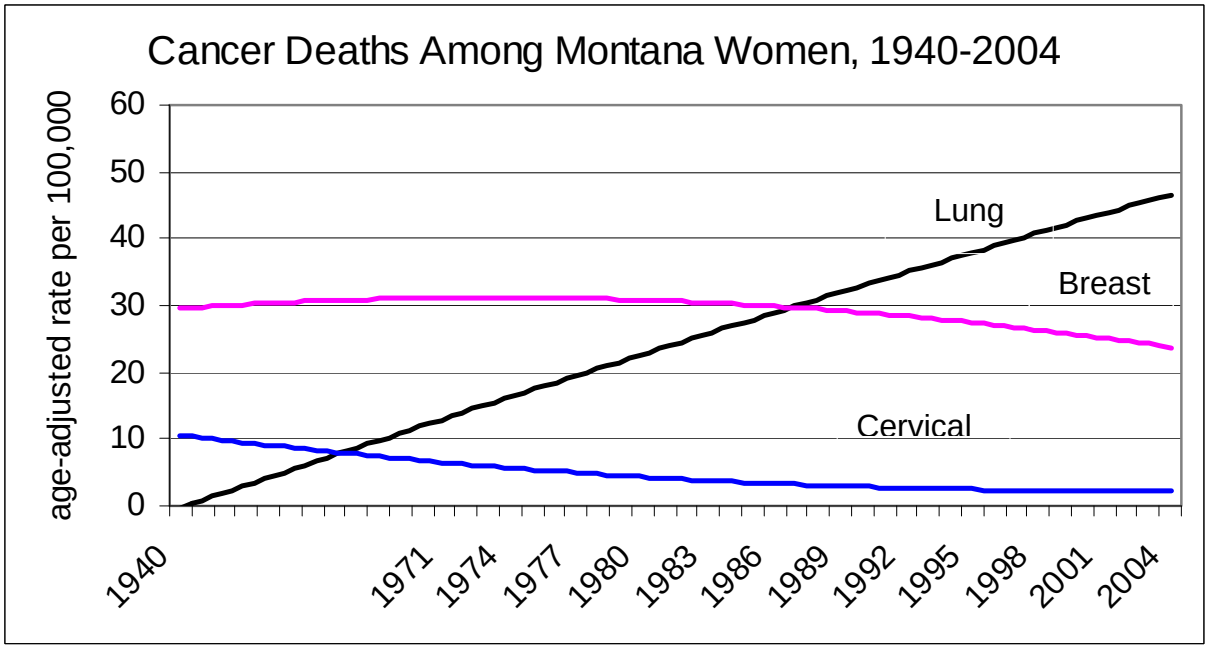
Montana Task Force on Cervical Cancer

Report to the Children, Families, Health and Human Services Interim Committee

August 1, 2006



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Executive Summary

The Impact of Cervical Cancer in Montana

The Cervical Cancer Task Force wishes to preface the following remarks by acknowledging that each case of cancer is important and each affected life matters. However, Public Health must objectively assess disease burden on a population basis. Cervical cancer accounts for less than 1% of all newly diagnosed cancers and 0.5% to 1% of all cancer deaths in Montana each year. Consequently, from a Public Health perspective, the burden of cervical cancer in Montana is low. In addition, the majority of cervical cancer cases can be prevented by regular screening and treatment of precancerous conditions. Early detection of cervical cancer greatly improves survival.

Most women in Montana take advantage of screening by Pap test. However, approximately 14% of women do not receive screening in accordance with recommendations endorsed by the U.S. Preventive Services Task Force, the American Cancer Society, the National Cancer Institute, and the American College of Obstetricians and Gynecologists. There is continuing need for provider and patient education about the importance of screening, and continuing need for outreach and provision of screening services to underinsured and uninsured women so all women in Montana may take full advantage of the benefits of screening.

The task force recommends the following strategies or actions to the Department of Public Health and Human Services (DPHHS) to reduce the occurrence of and burden and costs caused by cervical cancer:

- Increase the number of women screened.
- Increase screening services to women who are rarely screened.
- Increase public awareness of the cause and nature of cervical cancer and the importance of screening and early detection.
- Monitor the use of HPV vaccine in the population of eligible girls and women in Montana.
- Continue to monitor data on screening trends, cancer incidence, and mortality.
- Work in collaboration with public funders to target women at higher risk for diagnosis.
- Expand cervical cancer screening services of the Montana Breast and Cervical Health Program (MBCHP).
- Promote insurance coverage for populations at risk for cervical cancer.
- Encourage insurers to pay for screening of all women.

Members of the Task Force on Cervical Cancer

In accordance with the provisions of Senate Bill No. 328, a Cervical Cancer Task Force was appointed by Joan Miles, Director, Montana Department of Public Health and Human Services (DPHHS), including obstetrician-gynecologists, a registered nurse, a physician in family practice, a member of the cancer research community, a DPHHS epidemiologist, and a cervical cancer survivor. The Task Force voted at its first meeting to add a pediatrician, American Indian health care providers and community members, and a representative from a county health department.

Carla Williams, MD, Board Certified in Obstetrics and Gynecology, Chair
Jessica Bailey, MD, Family Practice
Carol Ballew, PhD, Epidemiologist, Cancer Control Section, DPHHS
Yvonne Blackburn, RN, Montana American Indian Women's Health Coalition
Suzanne Christopher, PhD, Department of Health and Human Development, Montana State University
Terry Dennis, MD, MPH, Medical Director, Billings Area Indian Health Service
Mary Haag, PhD, FACMG, Laboratory Director, Department of Medical Genetics, Shodair Children's Hospital
Terri Hocking, RN, CIC, Montana Public Health Association
Maria Huntley, MD, Board Certified in Obstetrics and Gynecology
Lois Jefferson, Cervical cancer survivor
Karen Sloan, RN, CNP, Family Planning Nurse Practitioner, Hill County Health Department
Cathy White, MD, Pediatrician

Support Members

The following individuals were invited to attend Task Force meetings to provide information and expertise:

Senator Carolyn Squires
Joan Miles, Director, DPHHS
Steven Helgerson, MD, MPH, State Medical Officer, DPHHS
Sue Miller, Supervisor, Cancer Control Section, DPHHS
Todd Harwell, MPH, Bureau Chief, Chronic Disease Prevention and Health Promotion Bureau, DPHHS
Kathy Myers, Quality Assurance Nurse, Montana Breast and Cervical Health Program, Cancer Control Section, DPHHS
Joyce Burgett, RN, MN, Supervisor, Immunization Section, DPHHS
Laurie Kops, Supervisor, STD and HIV Section, DPHHS

The Task Force on Cervical Cancer met on the following dates:

January 27, 2006
March 31, 2006
May 12, 2006

We thank the members of the Cervical Cancer Task Force and the Support Members for their time and commitment to the preparation of this report.

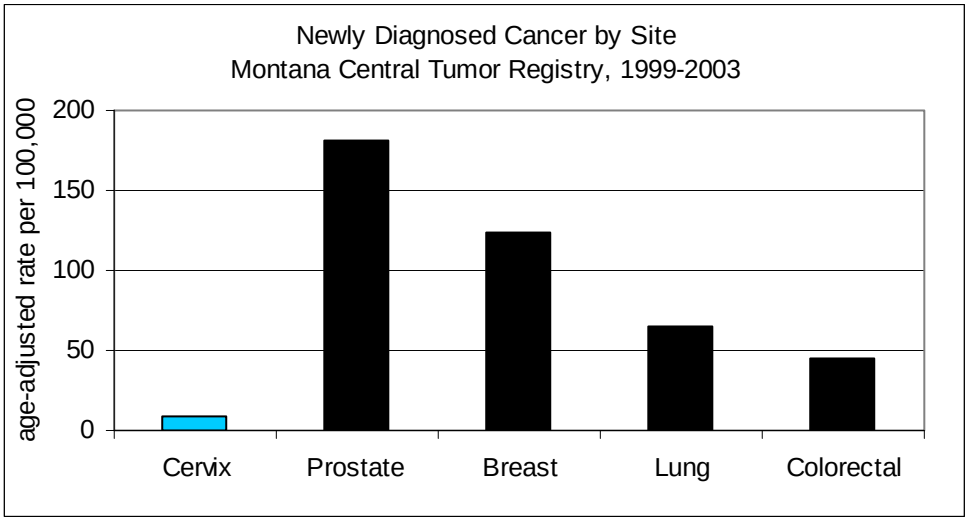
Report to the Children, Families, Health and Human Services Interim Committee from the Task Force on Cervical Cancer

In accordance with the guidelines set forth in Senate Bill No. 328, the Task Force addressed the following issues:

a.) Review statistical and qualitative data on the prevalence and burden of cervical cancer in Montana.

Although ***cervical cancer**** is one of the least common cancers in Montana and in the nation, each case of cancer is important and each affected life matters. Cervical cancer is now rare in Montana and in the United States and accounts for only 1% of all newly diagnosed cancers in Montana. The incidence of cervical cancer has decreased markedly in the past 50 years, due almost entirely to the wide use of the ***Papanicolau (Pap) screening test***.

The four most common cancers in Montana (prostate, breast, lung, and colorectal) are 18 times, 13 times, 7 times, and 5 times more common, respectively, than cervical cancer.[1]

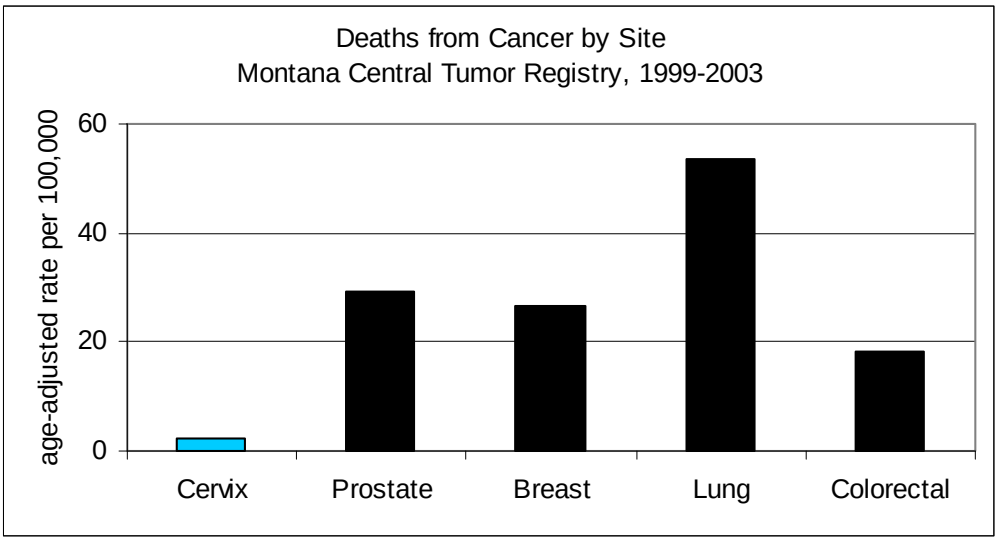


Twenty-nine Montana women were diagnosed with invasive cervical cancer in 2003,[2] compared with 873 men diagnosed with prostate cancer, 649 women diagnosed with breast cancer, 660 people diagnosed with lung cancer, and 467 people diagnosed with colorectal cancer.

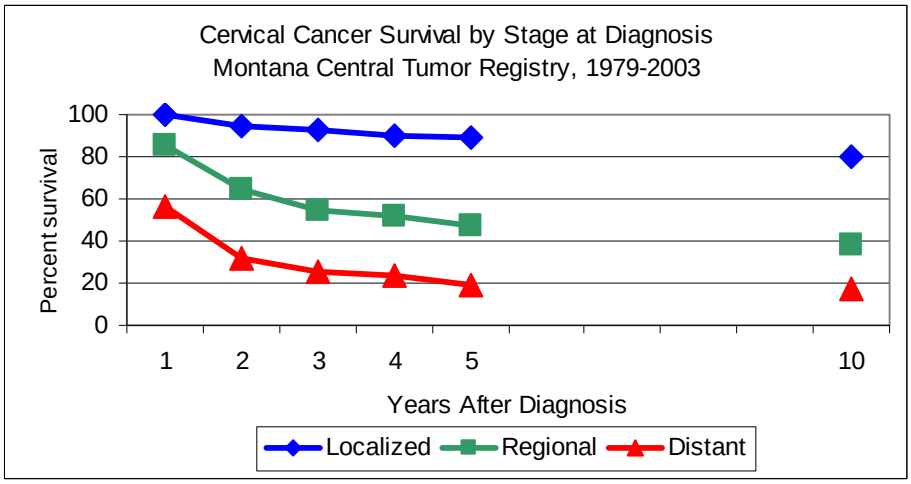
Death from cervical cancer is also rare in Montana. The age-adjusted mortality rate is 2.2 per 100,000 for cervical cancer, compared to 29.4 for prostate cancer, 23.7 for breast

* Terms in ***boldface italics*** are defined in the Glossary on page 10 .
[1] Montana Central Tumor Registry
[2] 2003 is the latest year for which the Montana Central Tumor Registry is complete at this time.

cancer, 53.6 for lung cancer, and 18.4 for colorectal cancer.[3] There were 12 deaths from cervical cancer in 2003, compared to 109 deaths from prostate cancer, 116 deaths from breast cancer, 534 deaths from lung cancer, and 164 deaths from colorectal cancer.



Survival after diagnosis of cervical cancer is excellent when it is found early through screening and early detection with the Pap test. Most women (90%) survive at least five years after diagnosis when cervical cancer is detected early, compared to 79% of men for prostate cancer, 85% of women for breast cancer, 35% of people for lung cancer, and 71% for colorectal cancer.[4]

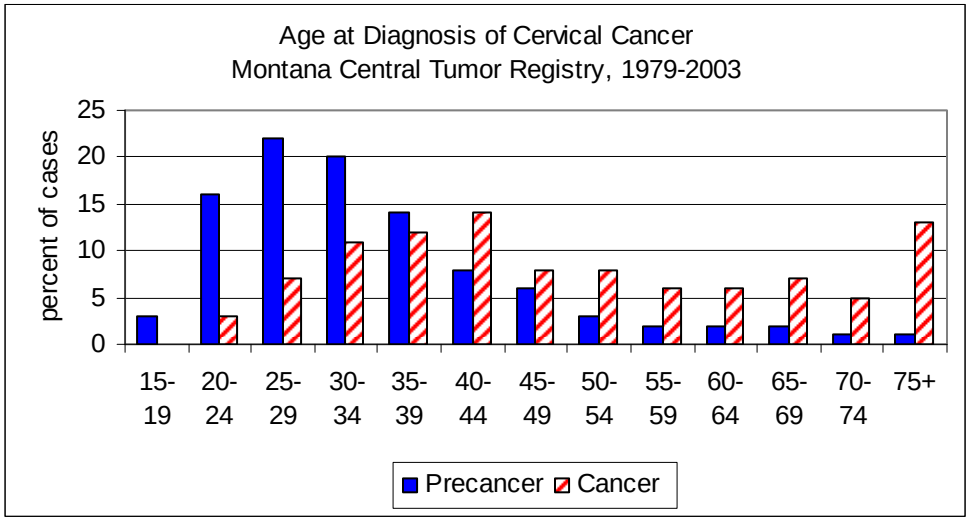


[3] "Cancer in Montana 1999-2003. Montana Central Tumor Registry Annual Report." July, 2005. Montana Department of Public Health and Human Services, available at www.cancer.mt.gov
[4] Montana Central Tumor Registry

Even more important, many women are spared ever developing cervical cancer because ***precancerous lesions*** are found using Pap test screening. Screening and prevention have reduced cervical cancer from the most common cause of cancer death among U.S. women in 1900 to one of the least common today. In Montana, death from cervical cancer decreased five-fold between 1940 and 2004 as Pap screening became an established standard of care for women.

Fortunately, approximately 86% of Montana women reported they have had a Pap test within the past two years. However, this means 14% of Montana women have not had regular screening. Screening is most common among women age 25-34 (95% of women in this age group have been screened) and least common among women age 65 and older (76% have been screened). In all women, screening is lower among those with less education and lower income.[5]

In Montana, precancerous lesions of the cervix are most commonly diagnosed in women between the ages of 20 and 39. Cervical cancer is most commonly diagnosed in women between the ages of 30 and 44, and again at age 75 and older.[6] It is therefore important that all women have access to screening throughout life, in accordance with current guidelines. In addition, older women who do not have a history of adequate screening should be screened to ensure that cancer or precancerous lesions are identified.



[5] Montana Behavioral Risk Factor Surveillance System 2004.
[6] Montana Central Tumor Registry

b.) Raise public awareness on the causes and nature of cervical cancer.

The task force identified the following settings as the best opportunities to raise public awareness on the causes and nature of cervical cancer and the importance of screening and early detection:

- Health care offices
- Family planning clinics
- Schools
- General community
- Work sites

The task force further outlined the following ways to increase public awareness about the causes and nature of cervical cancer and the importance of screening and early detection:

- Healthcare provider education
- Make recommendations to Office of Public Instruction (OPI) on health curriculum development to include guidelines on providing education in the schools across Montana
- Work with the universities to support development of community awareness efforts
- Mass (public service announcements) and small media (health education posters and brochures)
- Peer-to-peer health education. An example of this is the "Messenger for Health Program" on the Crow Reservation.

c.) Identify strategies and new technologies that are effective in preventing and controlling the risk of cervical cancer.

The U.S. Preventive Services Task Force (USPSTF) is the leading independent panel of private-sector experts in prevention and primary care. U.S. Public Law Section 915 mandates that the USPSTF convene to conduct scientific evidence reviews and develop recommendations for the health care community. The USPSTF conducts rigorous, impartial assessments of the scientific evidence for the effectiveness of clinical preventive services, including screening. The USPSTF's recommendations are considered the "gold standard" for clinical preventive services.

The USPSTF guidelines for cervical cancer screening are endorsed by the ***National Cancer Institute***, the American Cancer Society, and the ***American College of Obstetricians and Gynecologists***.

The USPSTF met in 2003 to consider cervical cancer screening. It made the following recommendations:

- All women who have been sexually active and have a cervix should have regular Pap tests, beginning at age 21 or at the onset of sexual activity, and at least every three years thereafter.
- Continued screening is not recommended for women age 65 and older who have had adequate recent screening with normal results.
- There is insufficient evidence to determine the relative merits of ***conventional Pap test screening*** ("dry mount") and the newer, ***liquid-based cytology***. At this time, the USPSTF is not recommending for or against a switch to liquid-based cytology.
- There is insufficient evidence to recommend for or against either routine or reflex testing for ***Human Papilloma Virus (HPV)*** as part of screening for cervical cancer.

Human Papilloma Virus (HPV) is a risk factor for developing cervical cancer, although the vast majority of women who are exposed to HPV will never develop cervical cancer. Vaccines against HPV are under development and one was approved by the Federal Drug Administration (FDA) in June 2006. The vaccine is effective against two of the 20 strains of HPV associated with cervical cancer; these two strains are believed to cause about 70% of cervical cancer in the US. The vaccine is also effective against two strains of HPV that are risk factors for genital warts; these strains are not associated with increased risk of cervical cancer. Shortly after the vaccine was approved, the federal Advisory Committee on Immunization Practice (ACIP) recommended use of the vaccine for girls ages 11 and 12. The ACIP allowed for vaccination of girls beginning at age nine as well as vaccination up to age 26; vaccination for women older than 26 was not recommended. The Director of the National Center for Immunization and Respiratory Diseases of the Center for Disease Control and Prevention (CDC) cautioned "[a]lthough an effective vaccine is a major advance in the prevention of genital HPV and cervical cancer, it will not replace other prevention strategies, such as cervical cancer screening."

The CDC's Division of Cancer Prevention and Control supports the recommendation that girls and women ages 9 to 26 be vaccinated against HPV but emphasizes that "[a]ll women receiving the HPV vaccine should continue to receive the Pap test according to established screening recommendations. HPV vaccination is not a substitute for routine cervical cancer screening (Pap tests) and is not intended to treat cervical cancers."

d.) Identify and examine the limitations of existing laws, regulations, programs, and services with regard to coverage and awareness issues for cervical cancer.

Programs and services to deliver Pap tests need to be widely available as well as culturally acceptable. Traditionally, women have received Pap tests as part of annual exams in order to get other services or health products such as birth control or estrogen replacement therapy. Women who receive health care in other contexts, those who do not have regular health care providers, and those who do not receive routine or regular health care may not receive regular Pap tests.

The Task Force identified three barriers that may limit women's access to Pap screening:

(1) At least two groups of women are not covered by existing reimbursement mechanisms for Pap tests:

- Those who are not eligible for public funds (***Title X clinics***, the Montana Breast and Cervical Health Program, and Medicaid).
- Those who have health insurance that does not cover screening procedures.

(2) In Montana, the scope of practice for performing Pap tests is limited to medical doctors, physician's assistants, and nurse-practitioners. In some other states, registered nurses who are not licensed as mid-level providers can perform Pap tests.

(3) ***The Montana Breast and Cervical Health Program (MBCHP)***, as one of the public funders of Pap tests, is currently able to serve women ages 50 and older. The task force recommends reducing the age for subsidized Pap tests under the MBCHP to 30. In Montana, 61% of precancerous lesions of the cervix are diagnosed in women under the age of 35 and 47% of invasive cervical cancer is diagnosed in women under the age of 45 (please see graph on page 3). Women younger than 30 have other avenues of public coverage, including Medicaid and Family Planning Clinics.

The retail price of the HPV vaccine is expected to be $120 per dose, or $360 for the required three-dose course;[7] the need for an additional booster is still under investigation. This expense may be a barrier to many potential recipients. Because the HPV vaccine has ACIP approval, it will be covered by the Vaccines for Children (VFC) program. The eligibility requirements for the VFC program include: children from birth through age 18 who are eligible for Medicaid, have no insurance or are underinsured (i.e., their insurance coverage does not include vaccinations), or are American Indian or Alaska Native. It is anticipated that

[7] http://www.cdc.gov/nip/vaccine/hpv/hpv-faqs.htm#18

the vaccine manufacturer will enter into a federal contract to allow states to purchase the HPV vaccine through the VFC program. States distribute VFC vaccines to registered public and private vaccine provider offices. The VFC program distributes and administers vaccines according to federal guidelines to be published in the Morbidity and Mortality Weekly Report (MMWR). At the time this report was submitted, an MMWR with guidelines for the HPV vaccine had not been released. Although it is anticipated that federal funds to support HPV vaccine for eligible children will be made available through the VFC program, the timing and amount of funding is not yet known.

e.) Include information and strategies relating to cervical cancer in a state comprehensive cancer control program.

The Task Force reviewed the Montana Comprehensive Cancer Control Plan 2006-2011 (attached to this report) as it relates to prevention, screening and early detection. References to the prevention, screening, and early detection of cervical cancer can be found on the following pages in the Montana Comprehensive Cancer Control Plan 2006 – 2011:

- Early Detection, page 20
- Screening Guidelines, page 21 and 25
- Reduce Barriers to Screening, pages 21, 31 and 32
- Increase Screening Rates, page 23
- Messengers for Health, page 24
- Broaden Coverage for Screening, page 26
- Patient/Provider Communication, page 34

f.) Facilitate coordination of and communication between state and local agencies and organizations.

The Montana Breast and Cervical Health Program (MBCHP) has established collaborative partnerships with more than 30 organizations throughout the state and has nearly 1,000 enrolled medical service provider partners. The MBCHP relies on Case Managers who provide support for enrolled women through all phases of outreach, screening, diagnosis and follow-up services as needed.

The Montana Cancer Control Coalition (MTCCC) is a diverse group of individuals and organizations working together to reduce cancer incidence, morbidity, and mortality for all Montanans through a statewide, coordinated, integrated approach to controlling cancer and ensuring quality of life and survivorship.

The MTCCC developed the Montana Comprehensive Cancer Control Plan 2006 – 2011 with broad public involvement throughout the process and from public comments.

g.) Receive and consider reports and testimony from individuals, including cervical cancer survivors, from leaders in the issue of cervical cancer, local health departments, community-based organizations, and voluntary health organizations, and from other public and private organizations statewide to learn more about contributions to prognosis, prevention, treatment, and improvement of cervical cancer prevention, diagnosis, and treatment in Montana.

The Task Force would like to thank three cervical cancer survivors who generously shared their experiences and answered questions. Two of the women were not getting regular Pap tests prior to their diagnosis. Both of these women experienced symptoms which led them to seek medical attention. The third woman had been getting regular Pap tests prior to her diagnosis. Her physician told her that her symptoms were probably a result of her age. Her husband then encouraged her to seek a second opinion – from a gynecologist. She was subsequently diagnosed with cervical cancer. All three shared how cervical cancer had affected their lives and the lives of their families.

Summary and Conclusions

In conclusion, the Cervical Cancer Task Force recommends the following strategies or actions to the Department of Public Health and Human Services to reduce the occurrence of and burden and costs caused by cervical cancer:

- Increase the number of women screened for cervical cancer.
- Increase the screening services to women who are rarely screened.
- Increase public awareness of the cause and nature of cervical cancer and the importance of screening and early detection.
- Monitor the use of HPV vaccine in the population of eligible girls and women in Montana.
- Continue to monitor data of screening behaviors and cervical cancer incidence.
- Work in collaboration with public funders to target those women who are at higher risk for cervical cancer.
- Expand services of The Montana Breast and Cervical Health Program (MBCHP) to younger women.
- Promote cervical cancer screening coverage for “at risk” populations.
- Encourage insurers to pay for screening of all women.

Glossary

American College of Obstetricians and Gynecologists (ACOG)
ACOG is a non-profit organization of women's health care physicians advocating highest standards of practice.

Cervical cancer*
Abnormal, disorganized growth of cells of the cervix that disrupts normal tissue or organ function and may invade (spread to) other organs if not treated.

Conventional Pap test*
Cervical cells are scraped from the surface of the cervix with a small spatula and are smeared on a glass slide and preserved with a spray fixative (coating). The slide is then examined under a microscope.

Human Papilloma Virus (HPV)*
A member of a large family of viruses that can cause temporary or persistent infections of the human genital tract. Some varieties are associated with an increased risk of developing precancerous changes of the cervix. Other varieties can cause genital warts. HPV is transmitted through sexual contact.

Liquid-based cytology*
Cervical cells are collected with a brush or other collection instrument. The instrument is rinsed in a vial of liquid preservative. The vial is sent to a laboratory where an automated thin-layer slide device prepares the slide for viewing.

Montana Breast and Cervical Health Program (MBCHP)
The mission of the MBCHP is to reduce breast and cervical cancer deaths among Montana women by providing ongoing quality screening services, diagnostic tests, and education in a manner that is appropriate, accessible, cost effective and sensitive to women's needs. The MBCHP provides mammograms, clinical breast exams, Pap tests and pelvic exams for the early detection of breast and cervical cancer. These services may be provided for free to eligible women.

National Cancer Institute
The National Cancer Institute (NCI) is a component of the National Institutes of Health (NIH), one of eight agencies that compose the Public Health Service (PHS) in the Department of Health and Human Services (DHHS). The NCI, established under the National Cancer Act of 1937, is the Federal Government's principal agency for cancer research and training.

Pap test*
The Papanicolau test is a procedure in which cells are scraped from the surface of the cervix for examination under the microscope. It is used to detect cervical cancer and precancerous changes that may lead to the development of cancer. Also called a Pap smear.

Precancerous lesions of the cervix*
Lesions are areas of abnormal tissue. Some forms of abnormal cells discovered in a Pap test are of uncertain significance and may return to normal on their own. Other forms of lesions have a high probability of progressing to cervical cancer if not treated promptly.

Title X clinics

For more than 30 years, Title X has been the nation's major program to reduce unintended pregnancy by providing contraceptive and related reproductive health care services to low-income women. Although public funds for family planning services also come from other programs (including Medicaid, state funds, Temporary Assistance for Needy Families (TANF), the Children's Health Insurance Program (CHIP), and the Maternal and Child Health and Social Services block grants), Title X is the only federal program dedicated solely to funding family planning and related reproductive health care services. In 1999, it helped to support 61 percent of all family planning agencies (Finer, et al., 2002). Title X accounts for 26 percent of the revenue of agencies receiving Title X funds (AGI, 2005a).

U.S. Preventive Services Task Force (USPSTF)

USPSTF is an independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services.

* Source: The National Cancer Institute, www.cancer.gov

Appendix

Montana Comprehensive Cancer Control Plan 2006 - 2011